4110-03

DUPLICATE OF ORIGINAL

DEPARTMEMNT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

[DOCKET NO. 77N-0409]

FIBRINOGEN (HUMAN)

REVOCATION OF LICENSES

43 FR 1131
1/6/78

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This document announces that all licenses issued for the manufacture of the biological product Fibrinogen (Human) were revoked as of December 7, 1977, and the sale, barter, or exchange of Fibrinogen (Human) by any manufacturer was prohibited as of that date. This action was taken at the request of the licensed manufacturers because the effectiveness of Fibrinogen (Human) is questionable and other products that carry lower risks of transmitting hepatitis may be used in its place. The Commissioner further gives notice that Fibrinogen (Human) already sold and delivered by the manufacturer may not be resold after July 1, 1978.

DATES: Effective date of revocation of all licenses for the manufacture of Fibrinogen (Human) was December 7, 1977. Existing stocks of Fibrinogen (Human) were prohibited from sale, barter, or exchange by the manufacturer as of that date. Fibrinogen (Human) in distribution as of that date is prohibited from sale, barter, or exchange by owners or custodians after July 1, 1978.

1997N.0409

NWL1

77-831

FOR FURTHER INFORMATION CONTACT:

Michael L. Hooton or Al Rothschild,
Bureau of Biologics (HFB-620),
Food and Drug Administration,
Department of Health, Education, and Welfare,
8800 Rockville Pike,
Bethesda, MD 20014,
(301-443-1920).

SUPPLEMENTARY INFORMATION: The Commissioner of Food and Drugs revoked product licenses issued to Merck Sharp & Dohme, Division of Merck & Co., Inc., establishment License No. 2; Cutter Laboratories, Inc., establishment License No. 8; E. R. Squibb & Sons, Inc., establishment License No. 52; Bureau of Laboratories, Michigan Department of Public Health, establishment License No. 99; and Travenol Laboratories, Inc., Hyland Division, establishment License No. 140, for the manufacture of Fibrinogen (Human) and prohibited the sale, barter, or exchange of Fibrinogen (Human) by the manufacturers as of December 7, 1977.

Fibrinogen is the component of blood that forms clots. Deficiencies or abnormalities of fibrinogen, whether hereditary or acquired, may lead to poor blood clotting and abnormal bleeding.

Fibrinogen (Human) is a biological product that has been licensed since 1947. The product has been recommended for treating patients who are bleeding and have low fibrinogen levels and for prophylaxis in patients with abnormally low fibrinogen levels when a major stress to the blood coagulation system is anticipated. Because the human

hemostatic process consists of a series of complex vascular and biochemical reactions, fibrinogen level alone is not always a valid measure of appropriate therapy. In most cases where the administration of fibrinogen is indicated, many abnormalities exist and simple infusion of fibrinogen will not produce normal coagulation. For this reason, the clinical effectiveness of Fibrinogen (Human) is difficult to assess, and there are few valid indications for its use.

Fibrinogen (Human) is prepared from plasma pooled from a large number of donors. Heat treatment to inactivate hepatitis B virus in Fibrinogen (Human) will adversely affect the potency of the product. For these reasons, Fibrinogen (Human) administration is associated with a higher risk of transmitting hepatitis B than products derived from single units of plasma. In those few clinical cases in which fibrinogen replacement is deemed necessary by the attending physician, Cryoprecipitated Antihemophilic Factor (Human) and other products prepared from single units of plasma may be used as a source of fibrinogen. This will diminish the hepatitis risk.

The Advisory Panel for Review of Blood and Blood Derivatives, established pursuant to § 601.25 (21 CFR 601.25), therefore recommended that Fibrinogen (Human) be withdrawn from the marketplace and that other products, such as Cryoprecipitated Antihemophilic Factor (Human), be used as a source of fibrinogen in the few clinical cases in which such

therapy is indicated. In response to the panel's recommendations, all licensed manufacturers of Fibrinogen (Human) requested that their licenses be revoked and waived the opportunity for a hearing pursuant to § 601.5(a) (21 CFR 601.5(a)).

Accordingly, the Commissioner announces the revocation, effective December 7, 1977, of all product licenses for the manufacture of Fibrinogen (Human). To facilitate the orderly transition by physicians, hospitals, and blood banks from the use of Fibrinogen (Human) to other appropriate products used for treatment of clotting problems, and pursuant to section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), the Commissioner is hereby giving notice that Fibrinogen (Human) which has already been sold and delivered by licensees may be resold through July 1, 1978, or the expiration date, whichever is earlier.

Dated: December 27, 1977.

DEC 27 1977

Joseph P. Hile
Associate Commissioner for
Compliance

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Debra E. Thomas